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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/627,578	07/25/2003	Christian Bohris	08340.105014	3000

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KING & SPALDING
1180 PEACHTREE STREET, NE
ATLANTA, GA 30309-3521

EXAMINER

LAMPRECHT, JOEL

ART UNIT	PAPER NUMBER
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3737

MAIL DATE	DELIVERY MODE
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10/28/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/627,578	Applicant(s) BOHRIS, CHRISTIAN	
	Examiner JOEL M. LAMPRECHT	Art Unit 3737	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 July 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-141 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-141 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>7/30/09</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-141 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mourad et al (US 6,875,176 B2) in view of Wurster et al (US 5,144,953). Mourad et al disclose an ultrasound system for evaluation of displacement based acoustic properties of tissues in a focal region including the evaluation of a correlation coefficient as a temporal measure of tissue attenuation and wave propagation (Figure 3, Col 25 Line 18-Col 26 Line 55), imaging of tissue regions with a probe-based scanner (Col 34 Line 1-25), evaluation of reference and actual values of correlation coefficients including temporal correlation and relaxation values of tissues over time (Col 6 line 55-61, Col 29 Line 10-Col 30 Line 30, Col 37 Line 20-Col 38 Line 50). Mourad et al disclose a concurrent transmit/receiving unit (Col 33 Line 45-Col 34 Line 25), for diagnostic ultrasound and a shockwave generator for pushing pulses (Col 33 Line 45-Col 34 Line 25). Mourad et al also disclose thresholding values for the cessation of therapy if a certain value is indicated as abnormal via an alarm mode (Col 43 Line 20-Col 44 Line 35) as well as standardization to a reference value (Col 41 Line 15-58). Furthermore, Mourad et al disclose a method of measuring relaxation of tissue to a standard curve to relate to the thresholding properties of the correlation coefficient (Col 36 Line 30-Col 37

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Line 20). Finally, Mourad et al disclose a display means for displaying correlation coefficient data, auto regulation data, statistical processes for discerning local maxima, minima, averaging, and other properties for analysis of the tissue in the region of interest, as well as concurrent display for localized properties of interrogated tissues (Claim 5, Fig 8, Col 43 Line 20-Col 44 Line 55, Col 33 Line 45-Col 34 Line 25, Col 38 Line 5-Col 40 Line 55).

Mourad et al do not disclose the use of a lithotripter in the sense of an ESWL device, rather they disclose an ultrasound pulse emitter for displacement of tissue and a diagnostic unit for assessment of that treatment or diagnostic therapy. Conventional shock wave lithotripsy uses similar values and principles to perform lithotripsy on an affected tissue (the values of the pushing pulses are higher and durations more abrupt typically, but the monitoring of tissues as taught by Mourad yields an assessment at least of the "effects", should there be any, of a therapy which causes calculi or tissue damage at a region of interest) and therefor attention is directed to the secondary reference to Wurster et al which discloses the use of a lithotripter in combination with an x-ray device for location and alignment of targeted tissue regions of the body (Abstract). Wurster et al disclose imaging integration with acoustic therapy for performing lithotripsy on concretions within the body (Col 3 Line 30-Col 4 Line 60). The destruction of calculi, as an effect of shockwave therapy, is a localized tissue therapy and as such it would have been obvious to one of ordinary skill in the art at the time of the invention to have used the device and methods of Mourad et al for diagnostic assessments of acoustic therapy with the lithotripsy methods and apparatus of Wurster et al for the purpose of

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facilitating monitoring and control of a similar acoustic wave therapy procedure within the body.

Mourad et al do not specifically disclose every limiting evaluation which can be performed to assess the therapeutic procedure, they rather focus on physiological effects of particular values diagnostically. It would have been obvious to one of ordinary skill in the art at the time of the invention to have utilized the data output in claims 5-7, 17-19, 26, 27, 31-33, and the associated disclosures mentioned above to optimize a therapy and create particular threshold values for the alarm device of Col 43 Line 20-Col 44 Line 35 as optimization of a parameter of a diagnostic procedure has been held as requiring only nominal skill in the art.

Response to Arguments

Applicant's arguments filed 7/30/09 have been fully considered but they are not persuasive. Applicant has argued that the monitoring system of Mourad et al is not-combinable prior art with the disclosure of Wurster et al. Examiner respectfully disagrees. Mourad et al, while directed to a diagnostic procedure, monitors the position and reflected waves from a focal region. The ultrasonic waves which are used in Mourad are not for destruction of calculi, but rather measure displacement and reflected echoes of the interrogated region. As currently claimed, Applicant is claiming a "hit control system" for a lithotripter, capable of monitoring the "effects" of a shockwave to a target area inside the body of a patient. A shockwave generator is disclosed, but the hit control system as claimed does not require effects to be measured specifically from the shockwaves generated by a lithotripter, rather an ultrasound unit is used for monitoring

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and correlation coefficient assessment. The reference to Wurster utilizes X-ray alignment to position the lithotripter and an ultrasonic position monitoring transducer to assess treatment (Col 2 Line 5-30). While the pushing pulses of the two systems are different, it is the monitoring feature that is currently being claimed in the instant application and based on the disclosures of Wurster in Col 2 Line 5-30 in view of the reference to Mourad et al, the "effects" of lithotripsy can be monitored and the concretion or tissue can be imaged (Col 2 line 15-20 of Wurster).

With regard to use of the system of Mourad et al for monitoring changes in the tissue, the following is offered in the abstract as motivation for the combination:

as well as diagnosis and monitoring of diseases and conditions that are characterized by physical changes in tissue properties. Methods and systems for localizing physiological condition(s) and/or biological response(s), such as pain, by targeting and selectively probing tissues using the application of focused ultrasound are also provided.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

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extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JOEL M. LAMPRECHT whose telephone number is (571)272-3250. The examiner can normally be reached on 8:30-5:00 Monday - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian L. Casler can be reached on (571) 272-4956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/BRIAN CASLER/
Supervisory Patent Examiner, Art
Unit 3737

JML